IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: DIGITEK PRODUCTS LIABILITY LITIGATION

MDL NO. 1968

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' RESPONSE AND MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION FOR ENTRY OF A "*LONE PINE* CASE MANAGEMENT ORDER."

On behalf of all Plaintiffs, the Plaintiffs' Steering Committee hereby files a Response and Memorandum in Opposition to Defendants' Motion for Entry of a "*Lone Pine* Case Management Order" that would require Plaintiffs to produce a case-specific expert or physician report on Digoxin toxicity, or produce medical records demonstrating that a treating physician diagnosed Digoxin toxicity and would respectfully show the Court as follows:

I. SUMMARY OF RESPONSE

The *Lone Pine* order proposed by Defendants is not a fair procedural mechanism, particularly because discovery in this case is in the incipient stages and Defendants production is such that Plaintiffs' have filed a motion to compel production of discovery and a motion to extend deadlines in PTO # 16. *Lone Pine* orders effectively function as untimely and unjust summary judgment devices and violate the discovery rules for expert witness disclosures and reports.

II. ARGUMENT AND AUTHORITIES

A. *Lone Pine* Orders Afford Defendants an Unfair, Prejudicial Advantage in the Litigation and Are Contrary to the Federal Rules of Civil Procedure

The fundamental problem with *Lone Pine* orders is that they emanate from procedural rules that do not specifically grant the authority for courts to issue such orders. It is not surprising, then, that Defendants cite not a single case from the Fourth Circuit in support of their Motion. That is because no such case exists. Indeed, despite Defendants' arguments to the contrary, *Lone Pine* orders are very much the exception, rather than the rule.

Instead of resorting to amorphous concepts such as inherent case management authority to justify a *Lone Pine* order, the Court should first look to existing procedural devices to address the issues raised, and should not ignore existing procedural rules and safeguards merely because mass tort cases are "different" from typical tort cases. Indeed, with no real guidelines to control the parameters and scope of *Lone Pine* orders, they are fertile ground for inconsistency, prejudice, and *ultra vires* action. *See* John T. Burnett, Lone Pine *Orders: A Wolf in Sheep's Clothing for Environmental and Toxic Tort Litigation*, 14 J. Land Use & Envtl. L. 53, 75-76 (1998).

More specifically, such *Lone Pine* orders are inherently unfair and prejudicial to Plaintiffs for at least two reasons: (1) they serve as improper, untimely substitutes for summary judgment motions, and (2) they ignore other existing procedural safeguards and rules.

First, Defendants *Lone Pine* request is the functional equivalent of the Defendants' filing a "no evidence" summary judgment motion long before discovery is complete in this litigation. In other words, little difference would result from Defendants filing a summary judgment motion, asserting that Plaintiffs have no evidence of injury, instead of their *Lone Pine* motion.

As with the grant of a *Lone Pine* order, such a summary judgment motion would put Plaintiffs to their proof, forcing them to obtain expert and physician reports posthaste to overcome the motion. However, with a *Lone Pine* Motion, Defendants would not be required to further participate in discovery at all, much less produce their own expert reports. *See Morgan v. Ford Motor Co.*, No. 06-1080, 2007 WL 1456154 at *7-8 (D.N.J. May 17, 2007). In *Morgan*, the court refused to grant defendants' *Lone Pine* motion because "[a]ny discovery must not be one-sided. . . . Defendants are not entitled to file what amounts to a summary judgment motion without first allowing the party opposing the motion a chance to conduct discovery." *Id.*

As Defendants know, significant due process concerns prohibit such summary judgment practice, which is why summary judgment is appropriate only "after adequate time for discovery." *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). Contrary to the self-serving procedure Defendants propose, summary judgment motions under Federal Rule of Civil Procedure 56 are intended to impose procedural safeguards that adequately protect the interests of ***all*** parties, while still addressing alleged factual deficiencies that *Lone Pine* orders are thought to remedy. In the ordinary course of pharmaceutical litigation, defendants typically move for summary judgment under Rule 56 after all discovery has been conducted. At that point, plaintiffs are required to offer evidence, expert witness testimony, and set forth specific facts that show a genuine triable issue of fact. Issuing a *Lone Pine* order, on the other hand, shortcuts the summary judgment process by demanding that Plaintiffs prove their *prima facie* cases prematurely and without the benefit of full or even reciprocal discovery by Defendants.

The Supreme Court of the United States has addressed the overall benefits of the existing procedural rules in *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506 (2002). The Court held that "under a notice pleading system, it is not appropriate to require a plaintiff to plead facts

establishing a prima facie case." *Id.* at 511. "This simplified notice pleading standard relies on liberal discovery rules and summary judgment motions to define disputed facts and issues and to dispose of unmeritorious claims." *Id.* at 512. The Court held that, with the limited exception of the kinds of cases described in Rule 9(b), requiring prima facie evidence at the pleadings stage would conflict with the notice pleading standard of Rule 8(a). *Id.* at 512-13.

Second, Federal Rule of Civil Procedure 26(a)(2) mandates reciprocal discovery. After pretrial disclosures, all parties are automatically mandated to disclose additional information, including expert witnesses. Although the timing of the disclosures is ultimately within the discretion of the courts, the spirit and letter of the rule requires the parties to exchange expert information simultaneously at least 90 days before the trial date. Fed. R. Civ. P. 26(a)(2)(C). If the evidence is intended solely to contradict or rebut testimony disclosed by another party, then the disclosure must be made within 30 days after the initial disclosure. *Id.* Rule 26 provides that one side should not be accorded the palpable procedural advantage gained by unilateral production of expert reports by its adversary.

All parties are entitled to due process. Appellate courts have held time and again that summary judgment cannot be granted without first affording the party against whom judgment is entered an opportunity to conduct discovery. As a general matter, federal litigation revolves around the generous and wide-ranging discovery provided by the Federal Rules of Civil Procedure and the Federal Rules of Evidence, which in turn operate from the basic underlying principle that court procedures should be fair to ***both*** sides.

B. The Vast Majority of Courts, in particular MDLs, Have Refused To Enter *Lone Pine* Orders, Notwithstanding Defendants' Reliance on Inapposite Cases

Despite Defendants' characterization of *Lone Pine* orders as "a valuable and often necessary tool in pharmaceutical multidistrict litigation," (Mot. at 5), *Lone Pine* orders are exceptional. Defendants cite four MDL proceedings in which courts entered a *Lone Pine* order, but the four orders cited by Defendants are dwarfed by the volume of MDL proceedings in which a *Lone Pine* or functionally equivalent case management order did not issue.[1] In all of the cases cited by Defendants in which a *Lone Pine* order was entered, the order was entered only after protracted discovery had already occurred, after a plaintiff failed to object to the entry of such an order, or after it became clear the pleadings were deficient in providing notice to the defendants. In almost every case in which a *Lone Pine* order is entered, the order comes after both plaintiffs and defendants have had the benefit of extensive discovery. Such orders are also sometimes entered in cases involving multiple distinct defendants because there is a problem of notice to the defendants or the court. *See Acuna v. Brown & Root, Inc.*, 200 F.3d 335, 340 (5th Cir. 2000) ("Neither the [100] defendant[s] nor the court was on notice from plaintiffs' pleadings as to how many instances of which diseases were being claimed as injuries or which facilities were alleged to have caused those injuries."). Finally, *Lone Pine* orders are sometimes entered simply because the plaintiffs do not oppose them. One or more of these elements is present in all of the cases cited by Defendants, and none are present in this case.

---

[1] *See In re St. Jude Med. Ctr., Inc. Silzone Heart Valves Prods. Liab. Litig.*, (MDL No. 1396); *In re Serzone Prods. Liab. Litig.* (MDL No. 1477); *In re Prempro Prods. Liab. Litig.* (MDL No. 1507); *In re Paxil Prods. Liab. Litig.* (MDL No. 1574); *In re Ephedra Prods Liab. Litig.* (MDL No. 1598); *In re Deep Vein Thrombosis Litig.* (MDL No. 1606); *In re Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, (MDL No. 1708); *In re Viagra Prods. Liab. Litig.* (MDL No. 1724); *In re Medtronics, Inc. Implantable Defibrillators Prods. Liab. Litig.* (MDL No. 1726); *In re Celexa and Lexapro Prods. Liab. Litig.* (MDL No. 1376); *In re Ortho Evra Prods. Liab. Litig.* (MDL No. 1742); *In re Human Tissue Prods. Liab. Litig.* (MDL No. 1763); *In re Seroquel Prods. Liab. Litig.* (MDL No. 1769); *In re Bausch & Lomb Inc. Contact Lens Solution Products Liab. Litig.* (MDL No. 1785); *In re Fosamax Prods. Liab. Litig.* (MDL No. 1789).

1. The cases cited by Defendants in which the plaintiffs did not oppose the entry of a case management order are inapposite

In three of the cases cited by Defendants, the plaintiffs did not oppose the entry of a case management order. In *Baker v. Chevron USA, Inc.*, 2007 WL 315346, (S.D. Ohio Jan. 30, 2007), the plaintiffs did not file a response in opposition or otherwise object to Chevron's motion for a *Lone Pine* order. Likewise, in *Abbatiello v. Monsanto Co.*, 569 F. Supp. 2d 351, 354 (S.D.N.Y. 2008), the parties agreed to the entry of a case management order, and the plaintiffs' injuries had "occurred over the course of more than forty years within a period which possibly ended over thirty years [prior to the suit]." Again, in *Grant v. E.I. du Pont de Nemours and Co.*, No. 91-55-civ-4H, 1993 WL 146634, at *1 (E.D.N.C. Feb. 17, 1993), plaintiffs did not oppose the defendants motion for entry of a case management order. The court entered a case management order only after extensive discovery had already taken place, and the order required both plaintiffs and defendants to present expert testimony in preparation for the trial of claims based on air and groundwater contamination. *Id*. at *1-5. Two of the cases cited by Defendants do not hold anything with regard to *Lone Pine* orders: *Steering Committee v. Exxon Mobil Corp.*, 461 F.3d 598, 604 n.2 (5th Cir. 2006), merely mentioned in passing a *Lone Pine* order in a footnote to an order affirming the denial of class certification, and *Judy v. Pfizer, Inc.*, 2005 WL 224088 (E.D. Mo. Sept. 14, 2005) does not mention a *Lone Pine* or case management order at all and deals simply with a defendant's right to remove under the Class Action Fairness Act.

2. The cases cited by Defendants in which the plaintiffs sued multiple defendants based on diverse theories of injury are irrelevant.

The non-binding cases cited by Defendants are exceptional and unlike the case before this Court. The source case for the order Defendants propose, *Lore v. Lone Pine Corp.*, No. L. 33606-85, 1986 WL 637507 (N.J. Super. Ct. Law Div. Nov. 18, 1986), is not binding on this Court, and has absolutely no precedential value in the state court system from which it issued. This is because unpublished New Jersey decisions are, by formal rule, bereft of precedential value. N.J. RULES OF COURT § 1:36-3. Notwithstanding the fact that *Lone Pine* has no precedential value, it was rendered under completely different and extreme circumstances. Plaintiffs sued "some 464 defendants," including the operator of a landfill and generators and haulers of toxic materials. *Lone Pine*, 1986 WL 637507, at *2. Plaintiffs, some of whom lived 20 miles from the landfill, alleged a variety of injuries including depreciation in property value and personal injuries ranging from allergies to skin rashes. *Id.* at *2-3. Likewise, *Acuna*, the only federal court of appeals case to embrace the entry of a *Lone Pine* order, involved similarly exceptional circumstances. In *Acuna* "approximately one thousand six hundred plaintiffs su[ed] over one hundred defendants for a range of injuries [related to uranium mining at a number of different locations and] occurring over the span of up to forty years." *Acuna*, 200 F.3d at 340. "Some plaintiffs worked in uranium mines and processing plants, while others alleged exposure to radiation or uranium dust or tailings through contact with family members who worked in the mines or through environmental factors such as wind and groundwater." *Id.* at 338. Due to the exceedingly diverse theories of recovery and the huge number of defendants, the court was concerned that the pleadings did not provide sufficient notice to defendants or the court. *Id*. at

340. Quite obviously that is not the case here. Plaintiffs' claims are based on a single product, Digitek®, and a small set of Defendants that manufactured and distributed that product.

3. **The cases cited by Defendants in which *Lone Pine* orders were entered late in the litigation after extensive discovery by both plaintiffs and defendants are distinguishable.**

The *Lone Pine* orders cited by Defendants that were granted by courts in MDL proceedings are also exceptional, and each occurred near the end of the litigation and after protracted discovery. In *In re Baycol Products Liability Litigation*, MDL No. 1431 (D. Minn. Mar. 18, 2004), Bayer had settled thousands of plaintiffs' cases prior to the entry of the *Lone Pine* order; therefore, the order served as a device at the ***end*** of the litigation to cull through the remaining cases. The same is true for *In re Bextra & Celebrex Marketing Sales Practices & Products Liability Litigation*, MDL No. 1699 (N.D. Cal. Aug. 1, 2008). When the *Lone Pine* order was entered in *Bextra*, Pfizer had already settled with many individual plaintiffs, significant discovery had occurred, including expert and scientific testimony, and the remaining litigants were engaged in settlement negotiations and pretrial preparation. In *In re Rezulin Products. Liability Litigation*, 441 F.Supp. 2d 567, 569-570 (S.D.N.Y. 2006), a *Lone Pine* order was entered "[a]fter extensive discovery" and after one theory of general causation relied on by some plaintiffs had been excluded under *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). The *Lone Pine* order in *Rezulin*, again occurring well into the litigation and discovery process, was intended to determine whether plaintiffs who had relied on "the silent injury" theory still had "good grounds . . . to continue prosecuting [their] claim[s] in light of the *Silent Injury* and other decisions." 441 F. Supp. 2d at 570. In *In re Vioxx Products*

Liability Litigation, 557 F. Supp. 2d 741, 744 (E.D. La. 2008), the case had been "in state courts for over seven years and [the MDL court] for over three years" and "much discovery [had] taken place" prior to the entry of the *Lone Pine* order. The court in *Vioxx* stressed that "*Lone Pine* orders may not be appropriate in every case and, even when appropriate, may not be suitable at every stage of litigation. . . . [I]n the present case, a *Lone Pine* order may not have been appropriate at an earlier stage before any discovery had taken place . . . ." *Id.* Unlike *Vioxx*, very little discovery has occurred in this case, and in fact, Plaintiffs have filed a motion to compel the production of discovery from Defendants. Each of the *Lone Pine* orders cited by Defendants that were entered in MDL proceedings were entered at the close of the litigation after extensive discovery had already taken place. This case is in its incipient stages and not yet ripe for an end game wrap-up.

In contrast to the cases cited by Defendants, just over one year into this litigation and approximately six months after the commencement of discovery, Defendants moved this Court to order Plaintiffs to prove their *prima facie* case in accordance with *Lone Pine*. *Lone Pine* orders are "not suitable at every stage of litigation," *id.*, and Defendants' Motion is conspicuously precipitous.

Ultimately, the cases cited by Defendants' establish only that a tiny fraction of courts have sometimes issued *Lone Pine* orders where (a) plaintiffs had sued dozens, if not hundreds, of unrelated defendants based on disparate theories of injury; (b) plaintiffs had already conducted ample discovery, or (c) plaintiffs did not oppose the entry of a case management order. This litigation falls into none of those categories.

4. Defendants' Reliance on the "FDA Reports" is Unavailing

In support of Defendants' statement that "[t]he FDA conclusion about the small likelihood of harm strongly supports entry of a Lone Pine order," they again cite two non-binding and distinguishable cases. In *Lone Pine*, the EPA had issued a record of decision, "which was a summary of sixteen studies on the Lone Pine Landfill," that "indicate[d] that there was no problem with ground water contamination, nor indeed with the transport of pollution by air, ground water or surface water." 1986 WL 637507 at *1, 2. In *Cottle v. Superior Court of Ventura County*, 5 Cal. Rptr. 2d 882, 3 Cal. App. 4th 1367, 1372 (Cal. Ct. App. 1992), the California Department of Health Services had issued a "remedial investigations report" as well as a "final report" that concluded that "the wastes . . . d[id] not pose any significant risks to public health or to the environment." In this case, the FDA has issued no report and has made no final determination based on any sort of scientific investigation. The so-called "determination" cited by Defendants comes from the FDA's website in which the FDA responds to the myth that "[t]here are quality problems with generic drug manufacturing." Facts and Myths about Generic Drugs (last updated July 10, 2009), http://www.fda.gov/ Drugs /ResourcesForYou /Consumers/ BuyingUsingMedicineSafely/ UnderstandingGenericDrugs/ ucm167991.htm. The FDA uses the "recent recall of generic digoxin (called Digitek)" as an example of the FDA's "aggressive action" and "active[] engage[ment] with [the manufacturers of Digitek] to ensure that **ALL** potentially affected lots of Digitek tablets have been recalled." *Id.* The FDA simply uses the Digitek® recall as an example of its own quality enforcement measures. The FDA in no way purports to provide any official determination about the effect of the out of specification tablets that reached the market, but simply says that due to "the lack of reported adverse events . . . [i]n [the FDA's] best judgment . . . harm to patients was very unlikely." *Id.* A website chronicling

the FDA's own quality-control efforts that provides no conclusion about the actual effect of the out of specification Digitek® is not an official report that would support the entry of a *Lone Pine* order.

5. The Vast Majority of Courts Have Not Issued *Lone Pine* Orders

A majority of courts have declined to enter *Lone Pine* orders or have overturned the entry of such orders because of the inequitable burden *Lone Pine* orders place on plaintiffs at the inception of litigation. *See generally*, *Kirsch v. Delta Dental of N.J., Inc.*, No. 07-186, 2008 WL 441860 (D.N.J. Feb. 14, 2008); *Morgan*, 2007 WL 1456154; *In re 2004 Dupont Litig.*, No. 04-229-DLB, 2006 WL 5097316 (E.D. Ky. March 8, 2008); *Simeone v. Girard Bd. of Educ.*, 171 Ohio App. 3d 633 (Ohio Ct. App. 2007); *Estate of Mancini v. Lexington Ins. Co.*, No. L-2228-03, 2006 WL 3359429 (N.J. Super A.D. Nov. 21, 2006). Plaintiffs are "denied the procedural protections of Civ. R. 56 [when a] court prematurely issue[s] a 'Lone Pine' order, which, in effect, bec[omes] a motion of summary judgment." *Simeone*, 171 Ohio App. 3d at 646. "Plaintiffs are not required to prove a prima facie case without the benefit of any discovery from Defendants." *Morgan*, 2007 WL 1456154 at *9. "Therefore, Plaintiffs must not be required to produce complete medical and real estate expert affidavits before any discovery, thereby giving Defendants and opportunity to attack the affidavits based on that justification for the lawsuit." *Id.* "Similar to Defendants, Plaintiffs must have an opportunity to contest the reasonableness of any experts relied on by their adversary." *Id.*

C. THERE IS NO REASON TO DISTURB THE CASE MANAGEMENT ORDERS ALREADY IN PLACE THAT REQUIRE DISCOVERY FROM BOTH PLAINTIFFS AND DEFENDANTS

Despite Defendants' claims to the contrary, Plaintiffs have already provided significant case-specific discovery to Defendants in this litigation. Plaintiffs have been required to unilaterally provide and verify extensive medical and non-medical information within a very compressed time period in the form of Plaintiffs' Fact Sheets and records authorizations. The PFS already obligates Plaintiffs to provide great detail regarding the nature of the claims pursued against Defendants. The information in the PFS (and from medical records available to Defendants[2]) establishes the foundational basis for Plaintiffs' prima facie case. In the cases where Plaintiffs have not provided the information required by the PFS, Defendants have already been granted the right to seek limited Rule 11 discovery or follow the deficiency process as set out by PTO # 16. As discovery proceeds, Defendants will garner additional case-specific information regarding Plaintiffs in due course.

Conveniently, Defendants have not mentioned their failure to meet discovery requirements. As mentioned in Plaintiffs' motions to compel and extend deadlines, Defendants have withheld documents for so long that Plaintiffs are forced to ask the Court for relief on a number of deadlines. To date Actavis has only produced only 65,782 pages of discovery. UDL has produced 202,206 pages with approximately 90% of that production occurring after September 1st. Mylan has produced 860,280 pages with approximately 94% occurring after September 1st. Mylan and UDL's delayed production and Actavis' incomplete production have prevented Plaintiffs from being able to properly prepare for depositions and zealously pursue

[2] While Defendants complain of the cost of medical records, the current system for collecting medical records was proposed by Defense Counsel.

their claims in the upcoming trial group. Defendants' efforts to create one-sided fact discovery into Plaintiffs cases will only be propelled further with the entry of a *Lone Pine* order.

While the Court certainly has an interest in ensuring that Plaintiffs are not pursuing cases without justification, the Court's ruling allowing limited Rule 11 discovery alleviates any concerns. Further, Plaintiffs are making an effort to self-police cases as shown by the recent increase in case dismissals.

Defendants have also completely ignored the Master Complaint, adopted in many cases, which includes allegations that "the amount of active ingredient was not consistent among Digitek® (Digoxin) tablets and the amount of active ingredient was inconsistent with the dose on the Digitek® (Digoxin) label." This includes pills that were manufactured with less than the stated amount of Digoxin, resulting in sub-therapeutic levels. An injury from a pill of this nature may not result in Digoxin toxicity. Clearly, a ruling requiring Plaintiffs to prove Digoxin toxicity would result in a denial of Due Process to these Plaintiffs.

The Court has prudently and justly charted a course in this MDL for completion of global discovery common to all cases transitioning to case-specific discovery that will include the trials of representative Plaintiffs jointly chosen by Plaintiffs and Defendants. The Court has focused the more individualized case-specific inquiries on the cases set for trial, and has required fact sheets and medical records authorizations from all Plaintiffs. In many cases, *Lone Pine* orders are sought as an ***alternative*** to a trial program like that which this Court has already determined to undertake. *See Morgan*, 2007 WL 1456154 at *9. The Court should deny Defendants' Motion.

III. CONCLUSION

Despite the popularity of *Lone Pine* orders with defense-oriented commentators, the truth is that such orders are extremely rare. Defendants are unable to cite a single case on point—from this Circuit or any other jurisdiction—supporting the Court's entry of a *Lone Pine* order here. In addition, the Court should reject the request for *Lone Pine* relief because it is inequitable and is inconsistent with the trial program already in place. The Court should deny Defendants' Motion.

Dated: September 24, 2009

Respectfully submitted,

On Behalf of the Plaintiffs' Steering Committee

s/Fred Thompson, III Esq.___
Fred Thompson, III, Esq.
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
Co- Lead Counsel

Carl N. Frankovitch, Esq.
Frankovitch, Anetakis, Colantonio & Simon
337 Penco Road
Weirton, WV 26062
Co- Lead Counsel

Harry F. Bell, Jr., Esq.
The Bell Law Firm PLLC
P. O. Box 1723
Charleston, WV 25326
Co-Lead and Liaison Counsel

CERTIFICATE OF SERVICE

I hereby certify that on September 24, 2009, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/Fred Thompson, III Esq.
Fred Thompson, III, Esq.
Motley Rice, LLC
28 Bridgeside Blvd.
Mt. Pleasant, SC 29464
Co- Lead Counsel